

DOE CONTRACTORS
SUPPLIER QUALITY INFORMATION GROUP
(SQIG)

NQA-1 Checklist

Revision 4

This revision reformats Revision 3 to remove text boxes in order to simplify checklist completion.
Content of the checklist has not changed from Revision 3.

Approved //original signed and on file//
Chairman

Date _____

SQIG SURVEY CHECKLIST

TABULATION OF SURVEY RESULTS

Quantity Item	Element	Total	Result		
		Attributes	Y	N	N/A
1	Organization	6			
2	Quality Assurance Program	15			
3	Design Control	16			
4	Procurement Document Control	6			
5	Instructions, Procedures and Drawings	3			
6	Document Control	4			
7	Control of Purchased Items and Service	15			
8	Identification and Control of Items	6			
9	Control of Special Processes	6			
10	Inspection	15			
11	Test Control	8			
12	Control of Measuring and Test Equipment	7			
13	Handling, Storage and Shipping	7			
14	Inspection, Test and Operating Status	3			
15	Control of Nonconforming Items	6			
16	Corrective Action	4			
17	Quality Assurance Records	13			
18	Audits	14			
Totals		154	0	0	0

No Deficiencies _____
Team _____

Deficiencies Noted _____ Audit
Lead Contractor _____

**SQIG SUPPLIER AUDIT
QUALITY/TECHNICAL EVALUATION OVERVIEW**

SUPPLIER _____

ADMIN. ADDR: _____ CITY _____ STATE _____ ZIP _____ PHONE _____ MANUF.
ADDR: _____ CITY _____ STATE _____ ZIP _____
PHONE _____

PROPOSED ITEMS _____
MAJOR PRODUCT _____

QA MANUAL REVISION/DATE _____
QA CONTACT/TITLE _____ SALES CONTACT _____

OTHER FACILITIES USED FOR PROPOSED PRODUCT? NO___ YES___
(IF YES, EXPLAIN) _____

TOTAL EMPLOYEES _____ QA/INSPECTION _____ MANUFACTURING _____
APPROX. SQ FT _____
NO. OF SHIFTS _____ SPECIAL PROCESSES? NO___ YES___
(IF YES, EXPLAIN) _____

PERFORM DESIGN? NO___ YES___

USE GOVT./CUSTOMER PROPERTY? NO___ YES___

PROCESS WITH AGE-DATED MATERIALS? NO___ YES___
(IF YES, EXPLAIN) _____

LIMIT ACCESS FOR PROPRIETARY REASON? NO___ YES___
(IF YES, EXPLAIN) _____

M&TE CALIBRATION IN-HOUSE? NO___ YES___
SUB-CONTRACT CALIBRATION? NO___ YES___

SUPPLIER QUALITY INFORMATION GROUP AUDIT CHECKLIST - NQA-1

Supplier:

Date(s):

1.0 ORGANIZATION

Plan Item No. 1.1 - Charts or Procedures

Are the supplier's organizational structure, functional responsibilities, and levels of communication for activities affecting quality documented? **[BR-1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 1.2 - Responsibility and Authority

Do persons or organizations responsible for verifying activities affecting quality have sufficient authority, access to work areas, and organizational freedom to: **[BR-1]**

- a. Identify Problems;
- b. Initiate, recommend, or provide solutions to quality problems through designated channels;
- c. Verify implementation of solutions;

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 1.3 - Access to Management

Do such persons or organizations have direct access to responsible management at a level where appropriate action can be effected? **[BR-1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 1.4 - Independence

Do such persons or organizations have sufficient independence from cost and schedule considerations? **[BR-1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 1.5 - Verification

Is quality achievement verified by persons or organizations not directly responsible for performing the work? **[1S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 1.6 - Documented Responsibility

Is the responsibility for control of further processing, delivery, installation or operation of nonconforming items documented? **[1S-1: 2.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

2.0 QUALITY ASSURANCE PROGRAM

Plan Item No. 2.1 - Formal Program

Has a documented quality assurance program been planned, implemented, and maintained in accordance with appropriate portions of NQA-1? **[BR-2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.2 - Scope

Does the program identify the activities and items to which it applies? **[BR-2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.3 - Conditions

Does the program provide for planning and accomplishment of activities affecting quality under suitably controlled condition, such as: **[BR-2]**

- a. Special controls, including environment;
- b. Special processes;
- c. Special test equipment;

- d. Special tools;
- e. Special skills to attain the required quality and verification of quality?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.4 - Verification

Does the program provide for necessary verification of quality, such as by inspection or test, audits, surveillance, and reviews? **[BR-2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.5 - Training

- a. Does the program provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained? **[BR-2]**
- b. Has the need for a formal training program been determined? **[2S-1: 2.4]**
- c. Have training activities been conducted to qualify personnel who perform inspections and tests? **[2S-1: 2.4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.6 - Assessment

Does management of the organizations quality assurance program regularly assess the adequacy of the program? **[BR-2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.7 - Qualified Personnel

Does the supplier's program specify activities that require qualified inspection and test personnel and the minimum requirements for such personnel? **[2S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.8 - Qualification Procedures

Has the responsible organization established written procedures for the qualification of inspection and test personnel? **[2S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.9 - Technical Indoctrination

Does the supplier's program have provisions for the indoctrination of personnel as to the technical objectives and requirements of applicable codes and standards and the quality assurance program elements which to be employed? **[2S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.10 - Performance Re-evaluation

Is the job performance of inspection and test personnel re-evaluated at periodic intervals not to exceed three years? **[2S-1: 2.6]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.11 - Qualification Records

Are records of personnel qualification established and maintained by the supplier?

[2S-1: 2.8]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.12 - NDE Certification

Is the certification of NDE personnel in accordance with the American Society of Non-Destructive Testing recommended practice No. SNT-TC-1A, and its applicable supplements? **[2S-2: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.13 - Administration of NDE Personnel Records

Does the supplier's program require written procedures for the control and administration of NDE personnel training, examination, and certification? **[2S-2: 2.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.14 - Auditor Training

Does the supplier's program require that auditors have, or be given appropriate training or orientation to develop their competence for performing required audits? **[2S-3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 2.15 - Auditor Certifications

Are lead auditors certified by the employer and does certification documentation include as a minimum:
[2S-3: 6.2]

- a.** Employer's name;
- b.** Lead Auditor's name;
- c.** Date of certification or recertification;
- d.** Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);
- e.** Signature of employer's designated representative who is responsible for such certification;

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

3.0 DESIGN CONTROL

Plan Item No. 3.1 - Definition and Verification

Does the supplier's program require that: **[BR-3]**

- a. Designs are defined, controlled and verified?
- b. Design adequacy be verified by persons other than those who designed the item?
- c. Design changes, including field changes be governed by control measures commensurate with those applied to the original design?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.2 - Inputs

Do the responsible design organizations identify, document, review and approve applicable design inputs? (such as: design bases, performance requirements, regulatory requirements, codes, and standards). **[BR-3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.3 - Input Changes

Are changes from approved design inputs, including the reason for the changes, identified, approved, documented, and controlled? **[3S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.4 - Design Documents

Do the supplier's design documents provide that: **[3S-1]**

- a. Appropriate quality standards be identified, documented and that their selection be reviewed and approved?
- b. Changes from specified quality standards (including the reasons for the changes) be identified, approved, documented and controlled?
- c. Design methods, materials, parts equipment, and processes that are essential to the function of the structure, system, or component be selected and reviewed for suitability of application?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.5 - Commercial Items

When a commercial grade item is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, is the item represented as different from the commercial grade in a manner traceable to a documented definition of

the difference? **[3S-1: 3B]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.6 - Design Analyses

Are design analyses performed in a planned, controlled, and documented manner?

[3S-1: 3.1]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.7 - Design Adequacy

Are design control measures applied to verify the adequacy of design such as: **[3S-1: 4]**

- a. Performance of design reviews;
- b. Use of alternate calculations;
- c. Performance of qualification tests?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.8 - Verification Results

Are the results of design verification clearly documented, with the identification of the verifier clearly indicated? **[3S-1: 4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.9 - Verification Prior To Use

Is the design verification completed prior to the functional use of the component, system or structure? **[3S-1: 4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.10 - Verification Extent

Is the extent of the design verification a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs? **[3S-1: 4.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.11 - Reviews

Does the supplier perform design reviews to provide assurance that the final design is correct and

satisfactory? **[3S-1: 4.2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.12 - Verification by Testing

Where design adequacy is to be verified by qualifications test: **[3S-1: 4.2.3]**

- a. Are tests identified?
- b. Is the test configuration clearly defined and documented?
- c. Are results documented and evaluated by the responsible design organization to assure that test requirements were met?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.13 - Modes and Conditions

Are the operating modes and environmental conditions considered when qualification testing is used to demonstrate adequacy of performance under conditions that simulate the most adverse conditions?
[3S-1: 4.2.3]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.14 - Design Changes

Are the changes to final designs, field changes, modifications to operating facilities, and non-conforming items dispositioned use-as-is or repair, justified and subject to design control measures commensurate with those applied to the original design? **[3S-1: 5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.15 - Change Review

Are changes approved by the same affected groups or organizations which reviewed and approved the original design documents? **[3S-1: 5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 3.16 - Records

Are the design documents and records which provide evidence that the design and design verification processes were performed in accordance with the requirements of NQA-1, collected, stored, and maintained in accordance with documented procedures? **[3S-1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

4.0 PROCUREMENT DOCUMENT CONTROL

Plan Item No. 4.1 - Document Content

Do the procurement documents include the following? **[4S-1: 2]**

- a. A statement of the scope of work?
- b. Technical Requirements?
- c. Identification of test, inspection, and acceptance requirements of the Purchaser?
- d. Requirement for suppliers to have a documented quality assurance program?
- e. Requirements for suppliers to incorporate appropriate quality assurance program requirements in subtier procurement documents?
- f. Rights of access to the supplier's plant facilities and records, for inspection or audit by the purchaser or his designated representative?
- g. Purchaser's requirements for reporting and approving disposition of non-conformance(s)?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 4.2 - Reviews

Does the suppliers's program provide for review of procurement documents and applicable changes to assure that documents transmitted to the prospective supplier(s) include appropriate requirements?
[4S-1: 3]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 4.3 - Review Prior To Award

Are such reviews performed and documented to provide objective evidence of satisfactory accomplishment prior to contract award? **[4S-1: 3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 4.4 - Exceptions Taken

Are changes or exceptions requested by the supplier analyzed to determine the effects such changes may have on the procurement documents or quality of the item or service?
[4S-1: 3C]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 4.5 - Proper Reviewer

Are procurement document reviews performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents? **[4S-1: 3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 4.6 - Changes

Are procurement document changes subject to the same degree of control as utilized in the preparation of the original documents? **[4S-1:4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Plan Item No. 5.1 - Procedures

Are the activities affecting quality prescribed by, and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances? **[BR-5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 5.2 - Acceptance Criteria

Do such documents include, or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities are satisfactorily accomplished? **[BR-5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 5.3 - Deviations

Are deviations from written procedures documented and authorized by appropriate personnel? **[BR-5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

6.0 DOCUMENT CONTROL

Plan Item No. 6.1 - Program

Does the supplier's program include a written document control system that provide controls for: **[6S-1: 2]**

- a. Identification of documents to be controlled and their specific distribution?
- b. Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents?
- c. Review of documents for adequacy completeness, and correctness prior to approval and issuance?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 6.2 - Minor Changes

Does the program clearly identify the types of minor changes that do not require review and approval, and the person authorized to make such decisions? **[6S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 6.3 - Major Changes

Verify that major changes are reviewed and approved by the same organization that originally reviewed and approved the document(s), unless other organizations are specifically designated. **[6S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 6.4 - Reviewer Access To Data

Does the reviewing organization have access to pertinent background data or information upon which to base their approval? **[6S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Plan Item No. 7.1 - Systematic Approach

Are the procurement activities planned and documented to assure a systematic approach procurement process? **[7S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.2 - Planning

Does the procurement planning provide documented identification of procurement methods and organizational responsibilities? **[7S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.3 - Supplier Selection

Is the selection of suppliers based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents? **[7S-1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. .7.4 - Extent of Verification

Is the extent of verification activities a function of the relative importance, complexity, and quantity of the items or services procured? **[7S-1: 5.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.5 - Verification Activities

Are the verification activities:

- a. Accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of suppliers? **[7S-1: 5.1]**
- b. Adequately documented? **[7S-1: 5.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.6 - Acceptance Criteria

Does the supplier have measures to provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria? **[7S-1: 6]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.7 - Acceptance Method

Does the purchaser's program require a certificate of conformance, source verification, receiving inspection or post-installation testing at the facility site as the prescribed methods used to accept an item or service from the supplier? **[7S-1: 8.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.8 - Certificate Validation

Are means provided to verify the validity of Supplier certificates and the effectiveness of the certification system? (Such as the performance of audits of the supplier, or independent inspection or test of the items) **[7S-1: 8.2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.9 - Source Verification Plan

Is source verification implemented in accordance with plans to perform inspections, examinations, or tests at pre-determined points? **[7S-1: 8.2.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.10 - Receiving

Is receiving inspection performed in accordance with documented procedures and inspection instructions, and are the results recorded? **[7S-1: 8.2.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.11 - Post Installation

Are post installation test requirements, and acceptance documentation mutually established by the Purchaser and Supplier? **[7S-1: 8.2.4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.12 - Service Acceptance

For procurement's involving services only; does the purchase establish acceptance criteria? **[7S-1: 8.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.13 - Nonconforming Items

Has the purchaser established and documented methods for the disposition of non-conforming items and services that do not meet procurement document requirements? **[7S-1: 9]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.14 - Dispositions

If the answer to 7.13 is yes:

- a. Do these methods contain provisions for evaluation of non-conforming items?
- b. Does the purchaser retain authority for the final disposition of the non-conformance based upon the supplier's recommendation?
- c. Are there provisions for verification of the implementation of the disposition?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 7.15 - CGI Receipt and Acceptance

After receipt of a commercial grade item, is the Purchaser required to determine that:

[7S-1: 10]

- a. Damage was not sustained during shipment?
- b. The item received was actually the item ordered?
- c. Are inspection and/or testing performed to assure conformance with the manufacturer's published requirements?
- d. Was the applicable documentation received with the item and was it reviewed for conformance?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Plan Item No. 8.1 - Measures Established

Are identification and control measures established to assure that only correct and accepted items are used or installed? **[BR-8]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 8.2 - Identification Method

Has identification been maintained either on the items or in documents traceable to the items? **[BR-8]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 8.3 - Lot I.D.

Are items of production (batch, lot, components, part) identified from the initial receipt and fabrication of the items up to and including installation and use? **[8S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 8.4 - Other Methods

Where physical identification of the items is either impractical or insufficient, has physical separation, procedural control, or other appropriate means been employed? **[8S-1: 2.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 8.5 - Traceability

When traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records, is required does the supplier program provide such identification and traceability control? **[8S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 8.6 - Limited Life Items

Are items having limited calendar or operating life or cycles identified and controlled to preclude use of items whose shelf life or operating life has expired? **[8S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

9.0 CONTROL OF SPECIAL PROCESSES

Plan Item No. 9.1 - Processes Controlled

Are the processes that affect the quality of items or services controlled? **[BR-9]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 9.2 - Documented

Are the special processes documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means? **[9S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 9.3 - Parameters Maintained

Do controls assure that process parameters and specified environmental conditions are maintained? **[9S-1: 3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 9.4 - Instructions

Have the special processes been performed in accordance with appropriate instructions which include or reference procedures, personnel and equipment qualification requirements? **[9S-1: 3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 9.5 - Responsibility

Does the supplier's program assign the responsibility to the organization performing the special processes to adhere to the approved procedures and processes? **[9S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 9.6 - References

Are the requirements of applicable codes and standards, including acceptance criteria for the process, specified or referenced in the procedures or instructions? **[9S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

10.0 INSPECTION

Plan Item No. 10.1 - Attributes and Methods

Are the characteristics to be inspected, and the inspection methods employed specified?

[BR-10]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.2 - Results

Are the inspection results documented? **[BR-10]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.3 - Independence

Have the inspections for acceptance been performed by persons other than those who performed or directly supervised the work being inspected? **[BR-10]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.4 - Independence

Do inspection personnel have reporting independence separate from the immediate supervisors who are responsible for performing the work being inspected? **[10S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.5 - Hold Points

When mandatory inspection hold points are required, beyond which work cannot proceed without the specific consent of the designated representative, are such specific hold points indicated in appropriate documents? **[10S-1: 3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.6 - Planning

Has the planning for inspection activities been accomplished and documented?
[10S-1: 4.1]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.7 - Planning

Does the inspection planning identify characteristics, methods, and acceptance criteria, and provide for recorded objective evidence of inspection results? **[10S-1: 4.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.8 - Sampling

When a sample is used to verify acceptability of a group of items, is the sampling procedure based on recognized standard practices? **[10S-1: 4.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.9 - In-Process

Are in-process inspections of items or construction performed for work activities where necessary to verify quality? **[10S-1: 5.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.10 - Indirect Controls

When inspection of processed items is impossible or disadvantageous, are indirect controls by monitoring of processing methods, equipment, and personnel provided? **[10S-1: 5.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.11 - Final Records Review

Does final inspection include a records review of the results for adequacy and completeness and resolution of any non-conformance identified by prior inspections? **[10S-1: 6.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.12 - Final Inspection

Does final inspection include the requirements to verify completeness, markings, calibration, adjustments, protection from damage, or other characteristics to verify the quality and conformance of the item to specified requirements? **[10S-1: 6.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.13 - Acceptance

Has final acceptance of items been documented and approved by authorized personnel?
[10S-1: 6.3]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.14 - Re-inspection

When modifications, repairs, or replacement of items are performed subsequent to final inspection, are such items re-inspected, or re-tested to verify acceptability? [10S-1: 6.4]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 10.15 - Records

As a minimum, does the supplier's inspection record identify: **[10S-1]**

- a. The item inspected?
- b. Date of inspection?
- c. Inspector?
- d. Type of observation?
- e. Results of acceptability?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

11.0 TEST CONTROL

Plan Item No. 11.1 - Planning and execution

Are test control measures that verify conformance of an item to specified requirements and verification of performance planned and executed? **[BR-11]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.2 - Attributes and Methods

Are the characteristics to be tested and test methods to be employed specified? **[BR-11]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.3 - Evaluation

Are test results documented, and their conformance with acceptance criteria evaluated?
[BR-11]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.4 - Documented Criteria

Are test requirements and acceptance criteria contained in applicable design or technical documents and are they approved by the organization responsible for the design of the item test? **[11S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.5 - Controls

Are the appropriate prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational test and operational tests, controlled?
[11S-1: 2]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.6 - Objectives and Prerequisite

Do test procedures include or reference test objectives and provisions for assuring that prerequisites for the given test have been met? **[11S-1: 4]**

Do prerequisite conditions include:

- a. That adequate instrumentation is available and used?
- b. That necessary monitoring is performed?
- c. That suitable environmental conditions are maintained?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.7 - Records

Do the test records, as a minimum, identify: **[11S-1: 5]**

- a. Item tested?
- b. Date of test?
- c. Tester or data recorder?

- d. Type of observation?
- e. Results and acceptability?
- f. Action taken in connection with any deviations noted?
- g. Person(s) evaluating test results?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 11.8 - Computer Programs

If computer programs are used for testing or test analysis:

- a. Do controls provide requirements for validation of the computer program and associated systems?
- b. Are verification tests that demonstrate the capability of the computer program to produce valid results for the test problems encompassing the range of permitted usage performed?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Plan Item No. 12.1 - Calibration

Are tools, gauges, instruments, and other measuring and test equipment calibrated, adjusted, and maintained at prescribed intervals, or, prior to use, against certified equipment having known valid relationships to nationally recognized standards? **[BR-12]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.2 - Selection

Is the selection of measuring and test equipment controlled to assure that such items are of proper type, range, accuracy, tolerance to accomplish the function of determining conformance to specified requirements? **[12S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.3 - Methods

Are the methods and intervals of calibration for each item defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control? **[12S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.4 - Control of Calibration Equipment

When measuring and test equipment is found to be out of calibration, is an evaluation made and documented of the validity of previous inspection or test results, and of the acceptability of items previously inspected or tested? [12S-1: 3.2]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.5 - Tagging and segregation

Are out of calibration devices tagged or segregated to control inadvertent use?
[12S-1: 3.2]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.6 - Handling and Storage

Does the supplier have adequate controls to assure that measuring and test equipment is properly handled and stored to maintain accuracy? [12S-1: 4]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 12.7 - Records

Are records maintained and equipment suitably marked to indicate calibration status?
[12S-1: 5]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

13.0 HANDLING, STORAGE AND SHIPPING

Plan Item No. 13.1 - Instructions

Have instructions for marking, labeling, packaging, shipping, handling, and storage of items been established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls? **[13S-1: 4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.2 - Conduct

Is the handling, storage, and shipping of items conducted in accordance with established work and inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures specified for use in conducting the activity? **[13S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.3 - Equipment or Environment

When required for particular items, is special equipment and special protective environments provided and verified? **[13S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.4 - Special Procedures

When required for critical, sensitive, perishable, or high-value articles, are specific procedures for handling, storage, packaging, and shipping and preservations used?
[13S-1: 3.2]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.5 - Special Handling

Are special handling tools and equipment utilized and controlled as necessary to ensure safe and adequate handling? **[13S-1: 3.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.6 - Equipment Inspection

Are special handling tools and equipment inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained? **[13S-1: 3.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 13.7 - Operators

Where applicable, are the operators of special handling and lifting equipment experienced or trained in use of the equipment? **[13S-1: 3.4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

14.0 INSPECTION, TEST AND OPERATING STATUS

Plan Item No. 14.1 - Traceability

Is the status of inspection and test activities identified either on the items or in documents traceable to the items? **[BR-14]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 14.2 - Indicators

Where it is necessary to assure that required inspections and tests are performed, and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated, is the status maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means? **[BR-14]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 14.3 - Authority

Has the authority for application and removal of tags, marking, labels, and stamps been documented? **[BR-14]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

15.0 CONTROL OF NONCONFORMING ITEMS

Plan Item No. 15.1 - Identified

Is the identification of non-conforming items accomplished by marking, tagging or other methods, that are legible and easily recognized, and do not adversely affect the end use of the item? **[15S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 15.2 - Analysis

Are non-conforming characteristics reviewed, including root cause analysis and recommended dispositions proposed and approved in accordance with documented procedure? **[15S-1: 4.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 15.3 - Hold for Disposition

Is further processing, delivery, installation, or use of non-conforming items controlled pending an evaluation, and approved disposition by authorized personnel? **[15S-1: 4.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 15.4 - Disposition Authority

Is the responsibility and authority for the evaluation and disposition of non-conforming items defined? **[15S-1: 4.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 15.5 - Technical Justification

Are dispositions, such as use-as-is, reject, repair, or rework, of non-conforming items identified and documented along with the technical justification? **[15S-1: 4.4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 15.6 - Reinspection

Are repaired or reworked items re-examined in accordance with applicable procedures, and with the original acceptance criteria, unless the non-conforming item disposition has established alternate acceptance criteria? [15S-1: 4.5]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

16.0 CORRECTIVE ACTION

Plan Item No. 16.1 - Identified and Corrected

Does the supplier's program require that conditions adverse to quality be identified promptly and corrected as soon as practical? [BR-16]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 16.2 - Cause and Corrective Action

In the case of a significant condition adverse to quality, is the cause of the condition determined and corrective action taken to preclude recurrence? [BR-16]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 16.3 - Documented and Reported

Are the identification, cause, and corrective actions for significant conditions adverse to quality documented and reported to appropriate levels of management? **[BR-16]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 16.4 - Follow up

Is follow-up action taken to verify implementation of corrective action? **[BR-16]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

17.0 QUALITY ASSURANCE RECORDS

Plan Item No. 17.1 - Records System

Is the records system defined, implemented, and enforced in accordance with written procedures, instruction, or other documentation? **[17S-1: 2.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.2 - Specified

Are applicable design specifications, procurement documents, test procedures, operational procedures, or other documents that specify the records to be generated, or supplied, maintained by the supplier?

[17S-1: 2.2]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.3 - Validated

Are documents that are considered valid records stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated? **[17S-1: 2.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.4 - Lifetime Classification

Does the supplier's system have provisions for the classification of lifetime or non-permanent records, and retention of such records when prescribed by contractual agreement with the Purchaser? **[17S-1: 2.7]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.5 - Non Permanent

Has the record period for non permanent records been established in writing? **[17S-1: 2.8]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.6 - Corrections

Does the supplier's system state that records may be corrected in accordance with procedures which provide for appropriate review and approval by the originating organization and these corrections shall be indicated with the date and the identification of the person authorized to issue such a correction? **[17S-1: 2.9]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.7 - Interim Protection

Do the individuals or organizations responsible for receiving records provide protection from damage or loss during the time that the records are in their possession? **[17S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.8 - Designated Personnel

Does each organization responsible for the receipt of records designate a person or organization responsible for receiving the records? **[17S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.9 - Specific Controls

Does the suppliers' receipt control system include: **[17S-1: 3.2]**

- a. A method for designating the required records?
- b. A method for identifying records received?
- c. Procedures for receipt and inspection of incoming records?
- d. A method for submittal of completed records to the storage facility without unnecessary delay?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.10 - Storage Procedure

Does the supplier's system provide a written storage procedure and assign responsibility for enforcing the requirements prior to storage of the quality records? [17S-1: 4.1]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.11 - Procedure Elements

Does the storage procedure include:

- a. A description of the storage facility?
- b. The filing system to be used?
- c. A method for verifying that the records received are in agreement with the transmittal document and that the records are legible?
- d. A method for verifying that the records are those designated?
- e. The rules governing access to, and control of the files?
- f. A method for maintaining control of, and the accountability for records removed from the storage facility?
- g. A method for filing supplemental information and disposing of superseded records?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.12 - Special Processed Records

Are there provisions for special processed records (such as radiographs, photographs, negatives, and microfilm) to prevent damage from excessive light, stacking, electro-magnetic fields, temperature and humidity? **[17S-1: 4.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 17.13 - Protection

Does the supplier's system provide that all quality records be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction? **[17S-1: 4.4]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

18.0 AUDITS

Plan Item No. 18.1 - Planned and Scheduled

Does the supplier's system provide for planned and scheduled audits to verify compliance with all aspects of the quality assurance program and determine its effectiveness? **[BR-18]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.2 - Procedures and Checklists

Does the supplier's system provide that the audits will be performed with written procedures or checklists? **[BR-18]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.3 - Documented and Reviewed

Does the supplier's system state that the audit results will be documented, reported to, and reviewed by responsible management? **[BR-18]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.4 - Follow up

Does the supplier's system provide that follow-up action be taken where indicated?
[BR-18]

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.5 - Coverage

Does the supplier's system require that internal and external quality assurance audits, or both, be scheduled in a manner to provide coverage and consideration with ongoing quality assurance program activities? **[18S-1: 2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.6 - Planning

Does the supplier's system provide that the auditing organization develop and document an audit plan for each audit which identifies the audit scope requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule and written procedures and checklists? **[18S-1: 3.1]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.7 - Auditor Independence

Does the supplier's system require that the auditing organization select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit? **[18S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.8 - Independence in Selection

Does the supplier's system require that in the case of internal audits, personnel having direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team? **[18S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.9 - Auditor Freedom

Does the supplier's system require that audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective? **[18S-1: 3.2]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.10 - Audit Team

Does the supplier system provide that the audit team be identified prior to the beginning of each audit, and contain one or more auditors and have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses? **[18S-1: 3.3]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.11 - Sign-Off by Team Leader

Does the supplier system require that the audit report be signed by the audit team leader? **[18S-1: 5]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.12 - Report Contents

Does the audit report contain the following?

- a. Description of the audit scope?
- b. Identification of the auditors?
- c. Identification of persons contact during audit activities?
- d. Summary of audit results including a statement of the effectiveness of the quality assurance elements which were audited?
- e. Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization?

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.13 - Management Actions

Does the supplier system require that management of the audited organization or activity shall investigate adverse audit findings, schedule corrective actions, including measures to prevent recurrence and notify the appropriate organization in writing of action taken? **[18S-1: 6]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed

Plan Item No. 18.14 - Records

Does the supplier's system require that audit records include audit plans, audit reports, written replies, and the record of completion of corrective action? **[18S-1: 8]**

Documents Reviewed/Activities Noted/Personnel Interviewed

Discussion

No Deficiencies Identified - Item Closed